Amendments to the Specification:

Please replace paragraph [0005] with the following amended paragraph:

[0005] Several attempts have been made to provide ambulatory or "wearable" drug infusion devices that are low in cost and convenient to use. Some of these devices are intended to be partially or entirely disposable. In theory, devices of this type can provide many of the advantages of an infusion pump without the attendant cost and inconvenience. Unfortunately, however, many of these devices suffer from disadvantages including user discomfort (due to the gauge and/or length of injection needle used), compatibility and interaction between the substance being delivered and the materials used in the construction of the infusion device, and possible malfunctioning if not properly activated by the user (e.g., "wet" injections resulting from premature activation of the device). ~~device.~~ Difficulties in manufacturing and in controlling needle penetration depth have also been encountered, particularly when short and/or fine-gauge injection needles are used. The possibility of needle-stick injuries to those who come into contact with the used device has also been problematic.

Please replace paragraph [0046] with the following amended paragraph:

[0046] Figs. ~~Fig.~~ 22(a) through 22(e) are multiple views of the reservoir subassembly of the patch-like injector or infusor system of Fig. 12;

Please replace paragraph [0052] with the following amended paragraph:

[0052] Fig. ~~Figs.~~ 28 is a top view from a first perspective angle of a fourth embodiment of a patch-like injector or infusor system prior to activation;

Please replace paragraph [0064] with the following amended paragraph:

[0064] Figs. 44 through 48 are cross-sectional views of the reservoir and valve subassembly of the patch-like injector or infusor system of Fig. 37 ~~in a closed position~~;

Please replace paragraph [0066] with the following amended paragraph:

[0066] Figs. 50 through 54 are views from a first perspective angle of assembly steps of the patch-like injector or infusor system of Fig. 37; ~~40~~;

Please replace paragraph [0074] with the following amended paragraph:

[0074] Fig. 67 is another [[a]] cross-sectional view of the improved valve embodiment of Fig. 65 in a closed ~~an open~~ position;

Please replace paragraph [0075] with the following amended paragraph:

[0075] Fig. 68 is a cross-sectional view of the improved valve embodiment of Fig. 65 in an open position and wherein the opening includes both tapered and flat surfaces;

Please replace paragraph [0087] with the following amended paragraph:

[0087] Figs. ~~Fig.~~ 84(a) through 84(c) are perspective views of a first, second and third improved Belleville spring and pin embodiment configuration;

Please replace paragraph [0095] with the following amended paragraph:

[0095] Fig. 93 is a cross-sectional view of a device embodiment using Belleville spring and pin friction to hold the device in a pre-activated ~~an activated~~ state;

Please replace paragraph [0098] with the following amended paragraph:

[0098] Fig. 96 is a perspective ~~cross-sectional~~ view of the improved arm/fluid path embodiment of Fig. 95;

Please replace paragraph [0103] with the following amended paragraph:

[0103] Figs. 101 through 105 are cross-sectional views of construction examples of [[in]] a patient needle manifold;

Please replace paragraph [0109] with the following amended paragraph:

[0109] Figs. ~~Fig.~~ 116(a) through 116(c) are illustrative views of a scotch-yoke function safety embodiment;

Please replace paragraph [0143] with the following amended paragraph:

[0143] Fig. 151 is another perspective view of the manifold spring of Fig. 150 in an unactivated position installed within an exemplary device;

Please replace paragraph [0145] with the following amended paragraph:

[0145] Fig. 153 is a perspective view of another improved manifold spring in an unactivated position installed within an exemplary device;

Please replace paragraph [0163] with the following amended paragraph:

[0163] Fig. 171 is an isometric view of the nest-type packaging system of Fig. 168 ~~169~~ having four devices in an up position for filling;

Please replace paragraph [0175] with the following amended paragraph:

[0175] In the embodiment shown in Figs. 1 through 4, as the push button 105 is pushed, three functions are achieved in an ordered and/or simultaneous fashion. First, the movement of the push button 105 opens at least one valve assembly 120 allowing fluid communication between the reservoir 150 and the patient needles 141. Second, the movement of the push button 105 dislodges the spring retention disk 135, releasing the Belleville spring 130, and third, the movement of the push button 105 removes the [[a]] support member 109 from the patient needle manifold 140 allowing the manifold 140 to travel as urged by a means, such as the fluid path arm 155 or a manifold spring (not shown).

Please replace paragraph [0176] with the following amended paragraph:

[0176] Specifically, the push button 105 includes the [[a]] series of inclines 107 which engage the spring retention disk 135 as the push button 105 is slidably moved, and release the Belleville spring 130 thereby pressurizing the contents of the reservoir 150. The push button

105 also engages the push valve 120, initiating flow between the now pressurized reservoir 150 and the manifold assembly 140. The push button 105 further removes or displaces one or more support members 109 from the patient needle manifold assembly 140, allowing the manifold 140 to be driven by a drive means, such as the fluid path arm 155 or one or more drive springs (not shown), and seat the patient needles 141.

Please replace paragraph [0177] with the following amended paragraph:

[0177] The push/pull valve assembly 120 of the embodiment shown in Fig. 1 is constructed to restrict flow between the reservoir chamber (i.e., as provided between elements 151 and 152 of [[or]] the reservoir 150), and the patient needle manifold 140 until pushed into an open position by the push button 105, and can be comprised of any number of valve assemblies 120, 222, 242 and 262, ~~and 226 and 228,~~ as described in greater detail below.

Please replace paragraph [0178] with the following amended paragraph:

[0178] A first embodiment of a push valve assembly 222 is shown in Figs. 5 and 6. Fig. 5 is cross-sectional view of the [[a]] valve assembly ~~122~~ in a closed position and Fig. 6 [[6B]] is cross-sectional view of the valve assembly of Fig. 5 in an open position. The valve assembly 222 includes a plastic button 223 slidably engaged within a rubber stopper 224 in fluid communication with the reservoir 150. The valve assembly 222 has as an initial state and an activated state, and includes a large diameter distal end having a distal set of radially projecting fins, or ribs 225, and a reduced diameter proximal end having a proximal set of detents 226. In the initial state, the valve 222 distal ribs 225 serve to prevent microbial ingress into the fluid path 227, and the proximal detents create a seal to trap the drug safely within the reservoir 150. Both sets of ribs 225 and detents 226 are performing critical tasks in

preventing fluid loss from inside the reservoir over long periods of time as well as preventing contamination of the drug from outside the reservoir over the same period of time.

Please replace paragraph [0180] with the following amended paragraph:

[0180] In the position shown in Fig. 5, the plastic button 223 includes the [[a]] reduced diameter proximal end having detents 226 seated securely within the rubber stopper ~~which~~ 124 and prevents any fluid escaping the reservoir 150. As the plastic button 223 is engaged and displaced within the rubber stopper 224 by the push button 105, an opening is created at the proximal end which allows fluid communication from the reservoir 150 as shown by the arrow in Fig. 6. The valve assembly 222 can be included in the reservoir subassembly 150, such that a continuous fluid path 154 can be provided by the reservoir subassembly 150 between the reservoir contents and the patient microneedles 141.

Please replace paragraph [0181] with the following amended paragraph:

[0181] A second embodiment of a valve assembly 242 is shown in Fig. 7. Fig. 7 is cross-sectional view of the [[a]] second valve assembly embodiment in an open position. The valve assembly 242 includes a plastic button 247, and is configured to operate as a pull valve. As shown in Fig. 7, when pushed forward, the plastic button 247 mateably engages the [[a]] reservoir 150 opening and prevents fluid communication from the reservoir 150. When pulled from the reservoir 150 opening, the gap produced allows fluid communication along the conical face of the button 247 and to the fluid path 154 toward the patient needle manifold (not shown).

Please replace paragraph [0184] with the following amended paragraph:

[0184] A third embodiment of a valve assembly 262 is shown in Fig. 8. Fig. 8 is cross-sectional view of the third ~~a fourth~~ valve assembly embodiment in an open position, and includes a plastic member 263, configured to operate as either a push or pull valve. As shown in Fig. 8, when pulled outward, the plastic member 263 obstructs the [[a]] reservoir opening and prevents fluid communication from the reservoir 150. When pushed forward the plastic member aligns an opening and allows fluid communication between the reservoir 150 and the patient needle manifold 140 (not shown).

Please replace paragraph [0189] with the following amended paragraph:

[0189] In the embodiment of Figs. 9 through 11, through a release means, such as a button (not shown), the hinged reservoir 287 is released, thereby releasing the Belleville spring 283 to then apply a force to the [[a]] flexible member 289 of the reservoir 287, compressing the contents against the [[a]] rigid member 288 of the reservoir 287. As shown in Fig. 10, when released, a spring 290 drives the manifold assembly 285 and reservoir 287 downward toward a patient's skin surface (not shown) and away from the disk 284, releasing the Belleville spring 283 and pressurizing the reservoir contents. Any number of valve assemblies can be used to establish the fluid path between the reservoir 287 and the manifold 285.

Please replace paragraph [0190] with the following amended paragraph:

[0190] In the embodiment shown in Figs. 9 through 11, upon release, the Belleville spring 283, manifold assembly 285, patient needle 286 and reservoir 287 are rotated into an activated and in-use position, and the desired three functions are achieved in an ordered

and/or simultaneous fashion. First and second, the activation allows the [[a]] spring 290 to rotate the reservoir 287 and manifold 285, which dislodges the spring retention disk 284, releasing the Belleville spring 283 and initiating flow from the reservoir 287. Third, the activation further allows the manifold 285 to travel as urged by the manifold spring 290 and seat the needles 286.

Please replace paragraph [0198] with the following amended paragraph:

[0198] In a third embodiment of the device, shown in Figs. 25 through 27, a push-button design 400 is shown wherein the activation and energizing of the device is also accomplished in a single multi-function/step process. Fig. 25 is an exploded view of the third embodiment of a patch-like injector or infusor system. Figs. 26 and 27 are cross-sectional views of the third ~~fourth~~ embodiment of the [[a]] patch-like injector or infusor system of Fig. 25 prior to, and subsequent to activation.

Please replace paragraph [0199] with the following amended paragraph:

[0199] In the third embodiment of the present invention shown in Figs. 25 through 27, an infusion device 400 includes a [[an]] push button 405, a reservoir subassembly 410, a Belleville spring retention handle 430, at least one Belleville spring 435, a reservoir film 440, a reservoir firm surface 442, a T pin 445, at least one patient microneedle 460, and a lower housing 470. The T pin 445 further includes a valve assembly 450, and the lower housing 470 can include an adhesive surface 475.

Please replace paragraph [0200] with the following amended paragraph:

[0200] As shown in Figs. 25 through 27, the embodiment of the present invention 400 can be constructed to provide a patch-like, wearable, self-contained substance infusion device that can be used to deliver a variety of medications to a patient. The device 400, provides the [[a]] hidden patient needle or needles 460 prior to and during use, and can be secured to a patient via the [[an]] adhesive surface 475. The pressurization of the contents of the reservoir (i.e., contents provided between the reservoir film 440 and the reservoir firm surface 442), can be achieved by removing or displacing the spring retention handle 430, thereby releasing the Belleville spring 435 to pressurize the reservoir contents. The device can then be further activated by slidably engaging the push button 405 inward towards the device. As the push button 405 travels, a stepped opening 406 in the button 405 releases a right angle member 446 of the T pin 445, thereby releasing the T pin 445 and allowing the patient needles 460 to drop as driven forward by a coil spring 408 disposed in a circular opening 410 within the T pin 445. ~~445.~~ In doing so, the patient microneedles 460 seat. As the T pin 445 drops, the opening 451 of valve 450 aligns with a fluid channel 452 in fluid communication with the reservoir, thereby creating a fluid path between the reservoir contents and the patient needles 460.

Please replace paragraph [0201] with the following amended paragraph:

[0201] Figs. 26 and 27 are cross-sectional views of the device 400 prior to, and subsequent to activation. In Fig. 26 (shown without the spring retention handle 430, lower housing 470, and the adhesive surface 475 for simplicity), the T pin 445 is held up by the [[a]] stepped opening 406, compressing the spring 408. Once the spring retention handle 430 is removed releasing the Belleville spring 435, the device 400 can be placed in position on the skin surface (not shown). As the button 405 is pushed, the stepped surface 406 releases the [[a]] right angle member 446 of the T pin 445, thereby releasing the T pin 445 and

allowing the patient needles 460 to drop as shown in Fig. 27. In Fig. 27, the patient microneedles 460 seat and the opening 451 of valve 450 aligns with the [[a]] fluid channel 452 in fluid communication with the reservoir, thereby creating a fluid path between the reservoir contents and the patient needles 460.

Please replace paragraph [0210] with the following amended paragraph:

[0210] In a fifth embodiment of the device, shown in Figs. 37 through 41, a push-button design 700 is shown wherein the activation and energizing of the device is also accomplished in a single multi-function/step process. Figs. 37 through 41 are cross-sectional views of the fifth ~~seventh~~ embodiment of a patch-like injector or infusor system. Figs. 42 through 44 are cross-sectional views of the reservoir subassembly of the patch-like injector or infusor system of Fig. 37. Figs. 46 through 48 ~~45 through 47~~ are cross-sectional views of a valve subassembly of the patch-like injector or infusor system of Fig. 37 in [[a]] closed and open positions, ~~position, respectively,~~ and Fig. 49 [[48]] is a ~~cross-sectional~~ view of a two-shot patient needle manifold subassembly of the patch-like injector or infusor system of Fig. 37. Figs. 50 [[49]] through 54 [[53]] are views of example assembly steps of the patch-like injector or infusor system of Fig. 37.

Please replace paragraph [0213] with the following amended paragraph:

[0213] Returning to Fig. 37, once the device 700 is properly positioned substantially as described above, the device 700 is activated by sliding the push button 780 inward towards the device. This slidable engagement drives an incline 782 towards the retention handle 730. As the incline 782 and retention handle 730 engage, the retention handle 730 is displaced from a position securing the Belleville spring 735, allowing the spring 735 to pressurize the reservoir 710. Specifically, this step releases the Belleville spring 735 allowing it to press

against the flexible film 740 of the reservoir 710, pressurizing the reservoir contents between the film 740 and the rigid portion 712. This activation step also serves to displace a support from beneath manifold 745, releasing the patient needle manifold 745 which is urged downward by the compression of the outer circumference arm 711 (or any number of springs as described above) and seating the patient needles 760. As further shown in Figs. 42 through 45, the outer circumference arm 711 can also extend about the opposite side of the reservoir 710 to provide a substantially continuous outer circumference arm that can act as a needle stabilizer, extending from the valve assembly 750 to the manifold 745. As shown in Fig. 42, the needle stabilizer can be provided about an arcuate path around the periphery of the reservoir, opposite to the needle conduit comprised of the outer circumference arm 711 and fluid path 713 therein, to stabilize the needles when the outer circumference arm 711 is used as the downward urging spring. Finally, the activation step also serves to open the valve assembly 750, establishing a fluid communication path between the reservoir 710 and the patient needles 760.

Please replace paragraph [0214] with the following amended paragraph:

[0214] Specifically, as shown in cross-sectional views Figs. 45, 46 and 47, the valve assembly 750 includes a plastic button 751 slidably engaged within a rubber stopper 752 in fluid communication with the reservoir 710. That is, for fluid communication the reservoir 710 and valve assembly 750 have a reservoir port 716 where the released contents of the reservoir first leave the containment of the reservoir, and have a needle port 718 where the released contents are directed to then travel to the needle. The valve assembly 750 has as an initial state and an activated state, and includes a large diameter distal end having a distal set of radially projecting fins, or ribs 753 forming a body seal, and a reduced diameter proximal end having a proximal set of detents 754 forming a reservoir seal at the reservoir port 716. As shown in Fig. 47, the reservoir seal of detents 754 is within the fluid flow path between ports 716 and 718, whereas only one side, the inner side, of the body seal is ever in contact

with the fluid flow path between ports 716 and 718. The outer side of the body seal of ribs 753 facing the button 751 are never in contact with the fluid flow path between ports 716 and 718. In use, the button 751 will eventually be pushed into an activated state by the movement of the push button 780 and the set of detents 754 will be advanced from engagement with the rubber stopper 752, which permits the drug to flow from the reservoir 710, past the detents 754 and into the fluid path 713. As stated above, a significant benefit to each embodiment described above includes the ability to achieve each step in a single push button action. Additionally, another significant benefit includes the use of a continuous fluid communication path comprised of the reservoir subassembly.

Please replace paragraph [0215] with the following amended paragraph:

[0215] A series of assembly Figs. 50 [[49]] through 54 [[53]] show an example assembly process for the above device. In Fig. 50, [[49,]] the lower housing 770, secured Belleville spring 730, and a push button 780 are prepared to receive the reservoir and upper housing. In Fig. 51, [[50,]] the reservoir 710, and manifold 745 (including an optional needle cap 719) are [[is]] prepared to drop into the lower housing 770 ~~as shown in Fig. 51~~. In Fig. 53, [[52,]] the upper housing 705 is then prepared to drop onto the lower housing 770 ~~as shown in Fig. 53~~.

Please replace the Table 1 between paragraphs [0223] and [0224] with the following amended Table 1:

Table 1

Path Component	Material
Reservoir	Polyethylene, cyclic olefin copolymer and/or Teflon
Reservoir Film	Metal-coated film, such as polyethylene, aluminum, polyester and/or nylon with a chemical tie layer, such as the product ~~such as the product~~ A83, manufactured by Beacon Converters of Saddle Brook N.J.
Patient Needle Manifold	Polyethylene and/or medical grade acrylic
Patient Needle	Stainless steel

Please replace paragraph [0243] with the following amended paragraph:

[0243] As shown in Fig. 61, ~~Figs. 61 through 63,~~ an improved valve assembly 1200 can consist of a push/pull valve rod 1206 seated in an opening 1201 within a housing 1203 in fluid communication with the reservoir (not shown) via path 1202. Figs. 61 and 62 [[63]] illustrate a pull valve 1200 and 1300 ~~1400~~ in a closed position, and Figs. 63 and 64 illustrate ~~Fig. 64 illustrates~~ a push valve 1400 and 1500 in a closed position.

Please replace paragraph [0245] with the following amended paragraph:

[0245] In Figs. 61 through 63, valve embodiments 1200, 1300 and 1400 are shown wherein the valve body 1206, 1306 and 1406 are constructed of an elastomer. The valves and valve ribs 1207, 1307 and 1407 are constructed, in part, of an elastomer which allows the elimination of a separate rubber plug or seal (i.e. 224 of Fig. 6). Additionally, the valves of Figs. 62 and 63, have a linear measurement sufficient to prevent the ribs 1307 and 1407 from contacting the fluid path escape opening ~~1204 and~~ 1304 and 1404, and possibly becoming damaged.

Please replace paragraph [0254] with the following amended paragraph:

[0254] In a second shot mold process shown in Figs. 72, 73 and 74, an elastomer overmold 1530 is provided over the core member 1520 of Figs. 69 through 71. Fig. 72 shows a perspective view of the overmolded core member 1520, Fig. 73 shows a side view of the overmolded core member 1520, and Fig. 74 shows a cross-sectional view of the overmolded core member 1520. The resulting valve member, or valve plunger rod includes distal sealing fins 1531 and proximal sealing fin 1532, which provide a surface which can create a seal within the valve opening equal to those provided by a separate plug. In doing so, the valve eliminates the need for a separate rubber plug or stopper in the valve. In an exemplary embodiment, the overmolded distal fins 1531 have a diameter of approximately 0.177 ~~0.0.177~~ inches and a thickness of approximately 0.016 inches. The overmolded proximal fin 1532 has a diameter of approximately 0.114 inches and a thickness of 0.02 inches and having a 45° tapered end extending axially therefrom.

Please replace paragraph [0257] with the following amended paragraph:

[0257] When the device is armed and the valve is in the closed position as shown in Fig. 79(c), ~~cross-sectional view 1550 in Fig. 79,~~ the fluid enters though the reservoir opening 1554 ~~a hole 1552~~ in the side of the second tube 1544 but is stopped by the side wall of the first tube 1542. In this position, the needles 1546 are attached to the first tube 1542 by a lever arm 1548, however, the fluid path between the needles and the inside of the first tube is closed from the fluid path of the second tube 1544, and the lever arm 1548 is positioned at an angle as to hold the needles 1546 above the skin of the user.

Please replace paragraph [0258] with the following amended paragraph:

[0258] When the device is activated, the lever arm 1548 is rotated such that the needles 1546 enter the skin. This rotation turns the first tube 1542 inside the second tube until the injection opening 1552 ~~a side hole 1554~~ in the first tube 1542 aligns with the reservoir opening 1554 ~~side hole 1552~~ in the second tube 1544 allowing fluid to flow. The fluid flows from the reservoir opening 1554 ~~side hole 1552~~ in the second tube 1544 through the injection opening 1552 ~~side hole 1554~~ in the first tube 1542 into the center of the first tube to the fluid path in the lever arm 1548, down the lever arm to and out the needles 1546 into the user's skin. The injection opening 1552 ~~side hole 1554~~ in the first tube 1542 is located such that it opens the fluid path only when the needles 1546 have entered the skin at the desired depth.

Please replace paragraph [0260] with the following amended paragraph:

[0260] The fluid path and valving of the embodiments shown in Figs. 75 through 79 are simplified and reduced into fewer parts by integrating the actions of opening the valve and inserting the needles into the same action and part. Additionally, the tubes 1542 and 1544

need not be complete circles but may be just arcs of circles. The fluid path may be a groove (not shown) down the outside of the first tube 1542 which aligns with the reservoir opening 1554 in ~~hole 1552 on~~ the second tube 1544. The fluid path may also be a groove (not shown) down the inside of the second tube 1544 which aligns with the injection opening 1552 in ~~hole 1554 on~~ the first tube 1542. The fluid path may further consist of a groove (not shown) in the inner wall of the second tube 1544 and the outer wall of the first tube 1542. [[1542. .]] In yet another variation, the lever arm 1548 could be attached to a rotating outer, or second tube 1544, with the inner, or first tube 1542 being stationary, such that the fluid flows from the first tube 1542 to the second tube 1544. In each variation, the valve type is one of aligning holes and/or grooves by integrating the movement of the needle insertion with the valve which opens the fluid path.

Please replace paragraph [0261] with the following amended paragraph:

[0261] In yet another rotating valve embodiment shown in Figs. 80 and 81, the infusion device can also use an improved rotating valve mechanism between a reservoir channel and a patient needle fluid path. Figs. 80 and 81 illustrate the valve assembly in a closed and open position, respectively. In Fig. 80, the fluid path openings 1557 and 1558 are not aligned due to the rotational position of the arm 1559. As the arm 1559 is rotated in the direction of arrow A, member 1555 is rotated within member 1556 into the position shown in Fig. 81, such as when the patient needles are seated, and the fluid path openings 1557 and 1558 become aligned and allow fluid flow.

Please replace paragraph [0266] with the following amended paragraph:

[0266] A sample of several, but not all pin 1564 geometry configurations which can use this basic principle are shown in Figs. ~~Fig.~~ 84(a), 84(b), and 84(c), and include a circular pin

(a), a broad lever pin (b), and a narrow lever pin (c) to provide rotational lifting. The round geometry as shown in configuration (a), allows a releasing force $F_1 \ldots F_n$ to be applied anywhere around the outer perimeter of the part (a), top or bottom, as shown in Fig. 85, to release the pin 84(a). The broad lever geometry as shown in configuration (b), allows a releasing force to be applied at a substantially narrower perimeter of the part to release the pin (b), as typically provided by a push button. The narrow lever geometry as shown in configuration (c), allows a releasing force to be applied from the side of the lever (c), rather than the end. In regard to configuration (a) of Fig. 84, application of the releasing force at an extreme edge of the circular pin (a), as shown in the force diagram of Fig. 85, results in a longer effective lever arm, thus lowering the ~~lower~~ required force.

Please replace paragraph [0276] with the following amended paragraph:

[0276] The device of Fig. 93 includes the [[a]] push button 1605, an upper housing 1610, a lower housing 1615, a reservoir pull valve assembly 1620, the [[a]] Belleville spring 1630, the [[a]] spring retention pin 1635, a manifold assembly 1625, and a reservoir 1650. The device further includes a flexible spring follower 1655. The device can further include an adhesive surface 1616 having a cover 1617, which is secured with a needle cap 1618 for one step removal. In the device shown in Fig. 93, as the push button 1605 is pushed, two functions are achieved in an ordered and/or simultaneous fashion, rather than the three functions of the device of Fig. 1. First, the movement of the push button 1605 opens the pull valve 1620 allowing fluid communication between the reservoir 1650 and the patient microneedles 1640 of the manifold 1625. The valve 1620 can be comprised of any number of pull valves as described above. Second, the movement of the push button 1605 dislodges the spring retention disk or pin 1635, releasing the Belleville spring 1630. However, the friction between the pin 1635 and the spring 1630, is also being used to hold the rotatable reservoir 1650 in a retracted position. When the push button releases the Belleville spring 1630, one or more manifold drive springs 1660 then rotate ~~rotates~~ the reservoir 1650

downward about a hinge mechanism 1652, and drive ~~drives~~ the needles 1640 into the patient's skin.

Please replace paragraph [0277] with the following amended paragraph:

[0277] The push button 1605 is provided with a tapered surface 1606 which further includes a slot 1608 (not shown) extending along a center of the tapered surface 1606 and through which the pin 1635 is allowed to travel. As the push button 1605 is pressed, the slotted tapered surface 1606 is forced to travel past the pin 1635, which forces the pin 1635 up the tapered surface 1606 and away from the spring 1630. The movement of the push button 1605 ~~1635~~ further serves to open the pull valve 1620. After a short distance, which is sufficient to open the pull valve 1620, the pin 1635 is lifted sufficiently to release the spring 1630 and the reservoir 1650.

Please replace paragraph [0285] with the following amended paragraph:

[0285] Sealing interlock examples for completing the assembly shown in Fig. 98 are shown in Figs. 99 and 100. In Fig. 99, a valve plunger rod 1732 is positioned within a cylindrical opening 1734 in the spring arm/fluid path housing 1720. The spring arm/fluid path housing 1720 includes a reduced diameter member 1736 which is mated with an opening 1702 in the reservoir 1700, and sealed with an O-ring 1738. The rod 1732 includes a number of ribs 1733 and an enlarged proximal end 1739 which functions substantially similar to those described above with reference to Figs. 5 and 6. In Fig. 100, the O-ring seal 1738 is replaced with an elastomeric exterior seal 1748 about the outside surface of the reduced diameter member 1736. ~~1746.~~ The remaining valve functions are substantially as described above in regards to Fig. 99.

Please replace paragraph [0302] with the following amended paragraph:

[0302] The device of Fig. 109 includes an upper and lower housing (not shown), a reservoir septum assembly 2740, a patient needle manifold assembly 2750, and a reservoir 2760. The [[A]] pivot arm 2770 is also provided, extending between the manifold 2750 and a valving needle 2780. An activation mechanism 2790 is shown, which can consist of any number of devices such as the push button of Fig. 1.

Please replace paragraph [0304] with the following amended paragraph:

[0304] The improvement embodiment shown in Figs. 109 and 110 includes the pivot arm 2770, ~~2779,~~ or tube, which includes a number of injection needles 2753 at a substantially perpendicular angle at one end, and the [[a]] single valve needle 2780 pointing in the opposite direction at the other end. The tube of the pivot arm 2770 has the [[a]] pivot point 2775 between the two ends that allows the infusing needles 2753 a range of movement necessary to penetrate the [[a]] patient's skin 2751, while also allowing the valving needle 2780 to penetrate the septum assembly 2740 leading into the reservoir 2760. The pivoting action is powered by one or more springs 2795 and is held in the armed position by the activation mechanism 2790.

Please replace paragraph [0306] with the following amended paragraph:

[0306] This improved activation embodiment of the present invention is a simpler device and includes a reduced number of parts relative to conventional devices and as such, is easier to assemble. For example, in conventional devices the infusion needles and the valving needle move perpendicular to each other and are typically connected by a tube. This improvement embodiment replaces the three commonly found moving parts of the fluid path

in other embodiments, that is, two pieces sliding at right angles and a flexible piece, with one moving part consisting of the [[a]] single continuous rigid rotating piece 2770. The flexible tubing, which can be hard to assemble, is replaced with an easier to assemble rigid part.

Please replace paragraph [0309] with the following amended paragraph:

[0309] As shown in Fig. 112, a clear-covered fluid chamber 1830 is positioned above a piston 1835 engaged with an upper magnet 1840 (in this example, having an [[a]] N pole above and an S pole below). The upper magnet, when activated, is repelled by a lower magnet 1845 (in this example, having an S pole above and an N pole below), forcing the piston 1835 into the contents of the chamber 1830. The contents are forced through an opening 1850 (which can be furthered valved as described above) and to a manifold 1855. The manifold can be constructed of a material with a low resistance to movement when driven by the manifold spring 1860, such as polypropylene or polyethylene.

Please replace paragraph [0310] with the following amended paragraph:

[0310] In yet another activation improvement embodiment shown in a device cross-sectional view in Fig. 113, the device includes an upper housing 1865, a lower housing 1870, a fluid reservoir 1875 (i.e., clear fluid chamber), a fluid path 1880, and an upper and lower magnet 1882 and 1884, respectively. The magnet of 1882 or 1884 can be replaced with a steel plate (not shown) which would also achieve the attraction force required. When activated [[()i.e.,]] (i.e., via a button or similar means), the attractive forces of the upper and lower magnets 1882 and 1884, or magnet and plate, coming together forces the contents from the reservoir 1875 via the fluid path 1880 and into a patient via a needle 1881. A center-fired patient needle mechanism incorporating any number of mechanisms described above, can be used to seat the needles 1881 during activation and results in a minimum of dead space.

Please replace paragraph [0318] with the following amended paragraph:

[0318] In a first example mouse-trap safety device shown in Fig. 37, the [[a]] push-button device 700 is shown wherein the activation and energizing of the device is accomplished in a single multi-function/step process as described above. Fig. 37 is cross-sectional view of an example patch-like injector or infusor system that is activated using a side push button and including the first improved safety embodiment of the present invention.

Please replace paragraph [0319] with the following amended paragraph:

[0319] The device of Fig. 37 includes the [[a]] push button 780, the [[an]] upper housing 705, the [[a]] lower housing 770, a mouse-trap door 790, a door latch 791, and a door pivot point 792. A flat spring 793 and a shield 794 are also provided and more clearly shown in Fig. 38. As the push button 780 is pushed, the movement of the button 780 opens at least one valve 750, dislodges the spring retention disk or pin 730, and removes a support member (not shown) from the patient needle manifold 745 allowing the manifold 745 to travel. The movement of the push button 780 also releases the door latch 791, however, as the device is adhesively positioned against a user's ~~users~~ skin, no movement of the door 790 is allowed.

Please replace paragraph [0320] with the following amended paragraph:

[0320] One aspect of this embodiment of the present invention is that in this state, the safety spring 793 is in a constant state of exertion towards an unbiased state (i.e., the state shown in Figs. 38 through 41). This constant exertion is countered by the surface upon which the device is attached (i.e., the skin of the patient) and the adhesive used to attach it. Therefore, the safety spring 793 is known to be working in a manner counterproductive to embedding needles 760 in a patient and keeping them embedded for a desired amount of

time. This force however, is necessary to the functionality of the mechanism, since it is this exerted spring 793 force which ensures eventual shielding of the needles 760 when the device is removed from the skin surface. Therefore to counter this force, a further aspect of the embodiment of the present invention is the inclusion of what could best be described as the [[a]] mouse-trap door 790.

Please replace paragraph [0324] with the following amended paragraph:

[0324] As shown in Fig. 116, the lifting is achieved using a scotch-yoke mechanism which is engaged with the patient needle manifold 1956, and is shown in a pre-use position (a), a substantially in-use position (b) and a post-use position (c). A torsional spring 1952 is provided with a pin or cam arm 1954 having a cam driven through a slot of the ~~slotted~~ manifold member 1956. As the spring 1952 exerts a rotational force, the arm 1954 drives the manifold 1956 into the skin surface (not shown) which also blocks further travel of the arm 1954. When removed, the arm 1954 is free to travel and in doing so, lifts and retracts the manifold 1956.

Please replace paragraph [0326] with the following amended paragraph:

[0326] Yet another embodiment of the present invention which includes lifting the needle or needles back out of the skin after they have been deployed uses a ramp mechanism as shown in Figs. 117 through 122. As noted above, the microinfusor includes at least one drive spring which acts to embed a needle or an array of needles into the skin of the user. The drive spring, by design, is positioned in such a manner that it can drive the needles into the skin. In the embodiment shown in Figs. ~~Fig.~~ 117 and 118, when the infusion is complete, a mechanism such as a ramp 1004 can be provided and positioned to allow the user to engage the ramp 1004 with the manifold 1000 or head of the needle or needle array, and by pushing

the ramp 1004 toward the manifold 1000 the needles (not shown) can be ramped up or lifted back out of the skin of the user. If the drive spring (not shown) however, is allowed to stay in position exerting force on the manifold 1000 of the needles, then this lifting of the needles is done against the force of the drive spring.

Please replace paragraph [0327] with the following amended paragraph:

[0327] As shown in Figs. 117 and 118, a passive retraction wedge design is shown having the [[a]] patient needle manifold 1000 having a substantially round pin 1002 extending from opposite sides thereof to engage an incline of the [[a]] ramp 1004 when the ramp is driven toward the manifold 1000 by a spring 1008. The ramp 1004 is secured from prematurely lifting the manifold 1000 by slots 1012 secured by an adhesive skin sensing pull-out member 1006. The entire assembly is disposed within an infusion device as described above. After use, the device is removed from the skin and the adhesive pull-out member 1006 is pulled downward out of the device as it is stuck to the skin surface (not shown). When this occurs, the slots 1012 of wedge 1004 are released from the pull-out member 1006 and the wedge 1004 is driven against the pins 1002 of the manifold 1000 as shown in Fig. 118. This lifts the manifold 1000 and the needles (not shown) are retracted into the device and the needle opening is covered internally by the wedge 1004.

Please replace paragraph [0328] with the following amended paragraph:

[0328] In this embodiment, the wedge 1004, or shield, is a molded part and is positioned between an activation button (not shown) and the manifold 1000. The [[A]] spring 1008 is also positioned between the wedge 1004 and the button. The spring 1008 is preloaded only enough to compensate for the difference in travel between the button and the necessary travel for retraction. The wedge 1004 is held in place by the skin-sensing pull-out member 1006.

The skin-sensing pull-out member 1006 is held by a slidable button component (not shown) in the side notches 1014 of the pull-out member 1006.

Please replace paragraph [0331] with the following amended paragraph:

[0331] Therefore, another version of the above embodiment is shown in Fig. 119. The concept of this embodiment includes the [[a]] manifold 1000 and a carriage 1005 that are launched forward together. The manifold drive springs (not shown), drive the carriage 1005 directly, and the manifold 1000 is coupled with the carriage 1005. The wedge 1004 in this case, is used to then separate the manifold 1000 from the carriage 1005 upon safety release by pushing the manifold free of detents 1007. Thus the drive springs of the manifold do not need to be overcome, as they remain exerted against the now independent carriage 1005.

Please replace paragraph [0337] with the following amended paragraph:

[0337] As shown in Fig. 120, a passive retraction slot design is shown having a slide 1015 having a pin 1016 extending from opposite sides thereof to engage a V-slot 1020 formed in a member 1022, and is driven within the slot 1020 by a pair of springs 1025. The entire assembly is disposed within an infusion device as described above. As noted above, the user begins operation of the device by pressing a means, such as the manifold or a button (not shown) substantially as described in the above embodiments, ~~embodiments)~~ to compress the springs 1025 as shown in Fig. 120. Once the device is activated by a release means, such as a user push button, the springs 1025 are released and drive member 1022 forcing the slide 1015 toward the skin surface as guided by slots 1020. The slide 1015 travels to the point of maximum needle insertion and is stopped from further downward travel by the skin surface (not shown), stopped from rearward travel by the springs 1025, and stopped from further forward travel by the ramped protrusions of the slots 1020. When the device is no longer in

contact with the skin, the slide 1015 is pushed down freely and travels further forward into the upward slope of slots 1020. The travel of the slide 1015 then exerts upward force on the manifold disposed beneath the slide 1015 (not shown) and retracts the needles back into the device and covers the hole, completely enclosing the needles.

Please replace paragraph [0339] with the following amended paragraph:

[0339] Another improved safety embodiment of the present invention is a passive fully enclosed shield as described below. Fig. 123 is a perspective bottom view of a device, illustrating a view of an embodiment of a bucket-type safety shield feature of an infusion device before activation, and Fig. 124 is a perspective bottom view of a device, ~~device ,~~ illustrating a view of the bucket-type safety shield feature after activation.

Please replace paragraph [0341] with the following amended paragraph:

[0341] As shown in Fig. 123, the needles 1040 are originally recessed within an opening 1035 on the [[a]] lower, adhesive covered surface 1045 of the device. The user secures the device on the skin with the adhesive surface 1045 and then presses the activation button 1042 to activate the infusion device. When the device is removed, the shield 1030 flips down and locks in place over the needles 1040 to prevent the user from seeing or touching the needles.

Please replace paragraph [0342] with the following amended paragraph:

[0342] The shield 1030 is a stamped and formed sheet metal part that is pre-loaded with the [[a]] torsion spring 1032. As can be seen in Fig. 125 illustrating a perspective view of the opened lower housing of the device showing the shield 1030 retracted within the device, the

front edge of the shield 1030 includes a lock arm 1034 that rests on a cross bar member 1036 of the device, thus holding it fixed. When the button 1042 is activated as shown in Fig. 126 illustrating a perspective view of the opened lower housing of the device showing the shield 1030 ready to rotate, the tabs 1044 on the button 1042 push the lock arm 1034 off the cross bar member 1036 to allow the shield 1030 to rotate under the load of the spring 1032 when clear of the skin surface. Fig. 127 illustrates a perspective view of the opened lower housing of the device after the shield 1030 is rotated. The tabs 1044 extend from the push button 1042 to also help prevent pinching of the skin between the push button and the cross bar member 1036 during activation.

Please replace paragraph [0343] with the following amended paragraph:

[0343] In yet another release embodiment, an additional arm (not shown) is provided at substantially 90 degrees to the lock arm 1034. This arm would point along the axis of movement of the button and hold the shield 1030 fixed before use. When the button 1042 is pressed, cam feature(s) (not shown) on the button 1042 push ~~pushes~~ the additional arm sideways so that it can drop through a slot and release the shield 1030 with only a small force applied. This also helps remove the tolerance sensitivity of button 1042 position while allowing the shield 1030 to rest lower in the device. This also can provide more room for the torsion spring 1032 and require less device height.

Please replace paragraph [0345] with the following amended paragraph:

[0345] In this embodiment, the lock is achieved with the lock [[an]] arm 1034 and/or snap configuration located at the front of the shield 1030. The force to engage the shield lock pushes the lock arm 1034 outward across the small dimension of the cross-section thus keeping the force low. The force to defeat the shield 1030 is applied across the large

dimension of the cross-section normal to the movement of the lock. This allows the force to engage the lock to be low while requiring ~~having~~ a much higher force to defeat the lock.

Please replace paragraph [0346] with the following amended paragraph:

[0346] The torsion spring 1032 can be loaded onto a pin (not shown) on the shield 1030, and a spring arm can be locked under tabs (not shown) on the back of the spring, thus preloading the spring and creating a stable sub-assembly. The shield assembly would be top down assembled into the bottom housing of the infusion device prior to the button sub-assembly ~~subassembly~~ by pressing a pivot means, such as a main bar (not shown) of the shield 1030 into two sets of snaps (not shown) within the lower housing to create the pivot. One arm of the spring can be released to press on the bottom housing, and one arm of the spring can be locked under tabs on the back of the spring, thus "energizing" the safety shield.

Please replace paragraph [0347] with the following amended paragraph:

[0347] The safety embodiment shown in Figs. 123 through 127 is ~~are~~ another example of a passive safety system that completely covers the needles 1040 with material. The material is constructed as a metal stamping, which allows smaller wall thickness. In doing so, the embodiment requires only two additional parts having a high strength to fail. Also, the minimal force applied to the skin by the shield is farther away from the needle contact point than other embodiments. The shield 1030 however, requires a degree of space within the device, which can make the device longer, and the shield 1030 presses on the skin during delivery. The shield opening 1035 further removes a large adhesive surface near the needles 1040. Also, as with most compressed spring mechanisms, such springs can be subject to creep, and there can be concerns regarding spring selection and the ability to construct pivot tubes as required.

Please replace paragraph [0349] with the following amended paragraph:

[0349] As shown in Fig. 128, a ~~the~~ button 1050 and not the housing holds a ~~the~~ shield 1055. When the button 1050 is pressed, the shield 1055 is released and rests on the skin substantially as described above. As the device is removed from the skin surface, the spring (not shown) flips the shield 1055 and a ~~the~~ ratchet mechanism 1060 at the pivot point engages ~~point, engaging~~ a catch 1061 on the device body as it rotates, such that the ratchet mechanism 1060 holds the shield 1055 in place. Fig. ~~Figure~~ 130 illustrates the ratchet mechanism 1060 in greater detail. Ratchet teeth 1059 are present on the shield 1055 arm 1057, and a corresponding wedge, or catch 1061 is located on the device. Any partial rotation is now locked.

Please replace paragraph [0353] with the following amended paragraph:

[0353] In the use of the embodiments of Figs. 131 through 134, ~~133,~~ the user prepares and uses an ~~the~~ infusion device 1060 substantially as described above. When the device is removed from the skin, an adhesive patch 1062 attached to a shield 1065 will pull the shield 1065 out and lock it into place before the adhesive patch 1062 releases the skin surface. The [[A]] safety housing, or shield 1065, is provided which includes a flat surface portion that is in contact with the patient's skin. The flat surface includes the [[an]] adhesive patch 1062 disposed thereon such that when the device is removed by the patient from the skin, the adhesive patch 1062 will act to deploy (i.e., retract or extract) the shield 1065 from the interior of the device, thereby shielding ~~the~~ patient needles 1067 which otherwise would be exposed upon removal of the device from the patient. The extended safety shield 1065 is then locked into place and prevents accidental injury or exposure to the patient needles.

Please replace paragraph [0354] with the following amended paragraph:

[0354] The shield 1065 is a stamped metal part that fits within the device 1060 and is held in place by a ~~the~~ button 1064 to prevent the shield 1065 from activating prior to use when the adhesive liner and needle cap (not shown) are removed. The adhesive patch 1062 is provided in substantially two parts, one on the bulk of the bottom surface of the device 1060, and one on the bottom surface of the shield 1065. When the device 1060 is removed, the two patches move independently and the shield 1065 is now mobile since the button 1064 has been pushed. In the embodiment shown in Figs. 133 and 134, ~~134 and 135,~~ a number of guide slots and tabs 1063 are provided with [[in]] the shield 1065. The shield 1065 is pulled out until it becomes trapped between the top of the slots and the tabs 1063, and is thereby locked into position by the angled tabs on the shield 1065.

Please replace paragraph [0357] with the following amended paragraph:

[0357] The embodiment includes a preloaded internal torsion spring 1070 which rests on a peg 1074 on a ~~the~~ manifold 1076. Two springs could be used if necessary. When a ~~the~~ button 1075 is pushed, the manifold 1076 is released and the spring falls off block 1071 and pushes a drive peg 1072 on the manifold 1076 to push the manifold 1076 downward to a seated position at the appropriate velocity. When the device is exhausted and it is removed from the skin, one of two things can occur. First, the manifold 1076 which is designed having extra over-travel, continues forward and the spring 1070 slips off the drive peg 1072, flips through 180 degrees, and catches a retraction peg 1074 on the manifold 1076, lifting the manifold 1076 thus retracting the needles (not shown). In an alternate version of the embodiment, the manifold 1076 is allowed to move sideways slightly, thus releasing the spring 1070 from the drive peg 1072 (which is somewhat shorter than the retraction peg 1074) to flip to the retraction peg 1074 on the manifold 1076, lifting the manifold 1076 thus retracting the needles.

Please replace paragraph [0361] with the following amended paragraph:

[0361] In Figs. 138 and 139, a hinged shield 1080 and 1085 is shown, respectively. When on the device, the hinged shields 1080 and 1085 are flat. The shields 1080 and 1085 are locked flat until buttons ~~the button~~ 1082 and 1086 are [[is]] pushed, respectively, in which case, the shields 1080 and 1085 are released but an adhesive holding the device to the body secures the shields 1080 and 1085 in a flat position against the skin. When the device is removed from the skin, the shields 1080 and 1085 "pop" up as urged by spring elements 1081 and/or an adhesive surface 1083, respectively, and are locked into place by tabs 1087.

Please replace paragraph [0362] with the following amended paragraph:

[0362] In each of these embodiments, the shields 1080 and 1085 can be a metal part sufficiently hinged at one point 1089 to secure rotation from the device. The hinged metal shield 1080 is driven by spring elements 1081 to an extended and locked position. Specifically, the shield 1080 can be constructed having a number of bent arms of the spring elements 1081 that ~~will~~ act as springs against the surface of the device. The bent arms of the spring elements 1081 are loaded against the bottom housing of the device and the button 1082 locks the front of the springs, typically at a point farthest from the hinge 1089, in the retracted position. When the button 1082 is pushed, the shield 1080 is free to rotate about the hinge 1089 but the skin keeps the shield flat. Upon removal of the infusion device from the skin, either the bent arms of the spring elements ~~spring fingers~~ 1081 alone, or in combination with the [[an]] adhesive 1083 as provided with spring 1085, pulls the shields 1080 and 1085 outward and locks it into place with a number of tabs 1087 at the front of the device.

Please replace paragraph [0364] with the following amended paragraph:

[0364] As shown in Fig. 140, an alternate version of the above embodiment includes a shield 1090 having a natural hinge which acts as the spring. The shield 1090 is held in the position shown in Fig. 140 by a ~~the~~ push button 1091. Once released, the shield 1090 is biased to the shape shown in Fig. ~~Fig~~ 141. Therefore upon activation and removal of the device, the spring 1090 is activated into the shape shown in Fig. 141 through the action of a natural hinge, covering the needles (not shown). The base of the device can further include at least one notch that can lock the rear edge of the shield 1090 as it travels.

Please replace paragraph [0366] with the following amended paragraph:

[0366] Still another passive design for shielding needles in a micro infusion device is that of rotating the needles either back out of the user or allowing the needles to "over rotate" to a safe position when the device is removed from the skin by the user. In the improved rotational shield embodiment shown in Fig. 142, the primary feature is the use of rotation to embed ~~the~~ needles 1101, and the use of the same or similar rotation "path" to remove the needles 1101 once a ~~the~~ skin surface 1104 is removed. In the embodiment shown in Fig. 142, a single needle-securing arm 1100 is rotated about a first axis 1102. As the needles 1101 contact the skin surface 1104, the needles 1101 are seated and travel about the axis 1102 is stopped. Upon completion and removal of the device from the skin surface 1104, the travel about the axis 1102 resumes, carrying the needle-securing arm 1100 back into the device (not shown). The needle-securing arm 1100 can also be rotated about a second axis 1106 to further shield the needles 1101 after use.

Please replace paragraph [0370] with the following amended paragraph:

[0370] In a first, or ready position shown in Fig. 143, the arm 1110 is at rest and the assembly is ready for activation by the user. This is typically the assembled and shipped configuration of the product. In a second, or spring cocked position shown in Fig. 144, a ~~the~~ button (not shown) is activated by the user and moves the member 1124 to the right. As the member 1124 is moved to the right by a force applied to pin 1120, the arm 1110 remains stationary and is driven into a deflected position by the movement of the cam opening 1114 about the stationary follower 1112. Since the pin 1120 and trigger 1118 are both attached to the button, each shift, placing the arm 1110 into this bent state by means of the cam opening 1114 and follower 1112. The spring is armed in this manner by the user at the time of use, which has the advantage over a pre-loaded assembly of eliminating the stresses and creep associated with a loaded spring. In this state, the trigger 1118 and latch 1122 are engaged and ready to fire by the user shortly before use.

Please replace paragraph [0375] with the following amended paragraph:

[0375] An improved flip-shield safety mechanism embodiment of the present invention is shown in Figs. 148 and 149. The function of the device is substantially the same as above except when the device is removed, the user flips a shield 1130 down and locks the shield 1130 in place to prevent ~~the~~ needles 1135 from being accessed.

Please replace paragraph [0387] with the following amended paragraph:

[0387] In Figs. 150 through 156, several improved manifold spring embodiments are shown. In Figs. 150, 151 and 152, perspective views of a first embodiment of an improved manifold spring are shown. Figs. 150 and 151 show the spring in a loaded, or flexed

position, and Fig. 152 shows the spring in a released, or relaxed position. A ~~The~~ spring 1140 includes a first and second adjacent member 1148 and 1145 coupled to produce a substantially acute angle when relaxed as shown in Fig. 152. When in a loaded position, the [[a]] first member 1148 is secured within an arc 1144 provided by the second member 1145. A large, perpendicular member 1142 is provided on the first member 1148 to engage a push button within the device to release the first member 1148 from the arc 1144 and apply pressure via a substantially curved element 1146.

Please replace paragraph [0388] with the following amended paragraph:

[0388] In operation, the loaded spring 1140 is positioned above a needle manifold 1151 within a device. The spring 1140 is positioned above the [[a]] needle manifold 1151, such as the manifold 520 in Fig. 34. Wherein Fig. 34 illustrates the[[, a]] spring 581 [[is]] provided to apply a force to the manifold 520, in yet other embodiments of the present invention, the spring 1140 can be positioned above the manifold 520 [[1140]] and provide a force to the manifold. In Figs. 150 and 151 the spring 1140 is held in a loaded state by the engagement between the first and second members 1148 and 1145. When the push button (not shown) is activated, the perpendicular member 1142 is engaged by contact with a button member 1159, moving the second member 1148 away from the stationary first member arc 1144, until the second member 1148 is released. Once released, the substantially circular contact area 1146 of the second member 1148 drives the manifold 1151. The circular contact area 1146 ensures spring to manifold contact is provided at a center point of the manifold 1151 throughout the expansion of the spring 1140. Such contact further ensures proper manifold travel. Still other embodiments of the improved manifold spring are shown in Figs. 153 through 156 and perform substantially as described above.

Please replace paragraph [0389] with the following amended paragraph:

[0389] In Fig. 153, the securing arc 1144 of Fig. 150 is replaced with a substantially larger member 1147 extending from a button engagement member 1149. As the button engages the member 1149, the member 1147 releases the spring and presses ~~pressing~~ the manifold 1151 forward, substantially as described above. Likewise in Fig. 155, the securing arc 1144 of Fig. 150 is replaced with an engagement between members 1141 and 1143 and when released, perform substantially as described above. Each includes a small detent means to prevent accidental releases.

Please replace paragraph [0391] with the following amended paragraph:

[0391] Step 1, shown in Fig. 157, illustrates a filling process. A partial cross-sectional view of a device 1150 shows a push button 1153 positioned adjacent to a ~~the~~ reservoir opening 1154. A hole 2153 is included in the push button 1153, which allows filling the device 1150 through the reservoir opening 1154 even after assembly. In step 2 shown in Fig. 158, a valve assembly 1156 is assembled within the reservoir opening 1154 after filling through the button hole 2153. The valve assembly 1156 can be assembled through the hole 2153, therefore, to use the button 1153 to actuate the valve 1156, the hole 2153 needs to be restricted in some manner. In step 3, a member 1158 is provided to close the button hole 2153 access, or window, to allow the activation of the valve 1156 as shown in Fig. 159. Once closed, as shown in Fig. 160, the push button 1153 is ready to be pressed, thereby activating the valve assembly 1156.

Please replace paragraph [0396] with the following amended paragraph:

[0396] To provide the embodiment of the present invention described above, a flexible material is provided as the membrane 1162. At the beginning of the injection, the "flexible sign" of the raised relief 1168 is applied on the flexible membrane 1162 and as such, the force applied to the raised relief 1168 is the force applied to the film 1162 and the reservoir contents, which yield to a great degree therefore little deformation of the raised relief 1168 appears. At or near the end of the infusion or injection, the membrane or film 1162 is in contact with the hard transparent part 1164 of the reservoir 1160, and the raised relief 1168 is compressed against the reservoir and the sign of the raised relief 1168 ~~1160~~ disappears.

Please replace paragraph [0413] with the following amended paragraph:

[0413] Other benefits associated with the embodiment described above include ~~includes~~ the ability to have the [[a]] flexible bag 1185 instead of the rigid box 1180 as part of the external packaging, then allowing a vacuum in the bag 1185 to provide a visual indicator of the package integrity. In this version, a lost vacuum indicates no integrity. Additionally, the [[a]] flexible bag 1185 is less expensive to provide than the [[a]] box 1180. In a preferred embodiment, a configuration is provided with the nest 1170 and the external bag 1185 having no vacuum, and an added second bag 1190 also without vacuum to prevent dust from coming into contact with the first bag.